Clinical Policy Title:	belantamab mafodotin-blmf
Policy Number:	RxA.660
Drug(s) Applied:	Blenrep™
Original Policy Date:	03/06/2020
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Multiple Myeloma (must meet all):

1. Diagnosis of RRMM;
2. Age ≥ 18 years;
3. Prescribed as monotherapy;
4. Member has received ≥ four (4) prior that include all of the following (a, b, or c);
   a. One anti-CD38 monoclonal antibody (e.g., Darzalex®/Darzalex Faspro™, Sarclisa®);
   b. One proteasome inhibitor (e.g., bortezomib, Kyprolis®, Ninlaro®);
   c. One immunomodulatory agent (e.g., Revlimid®, pomalidomide, Thalomid®);
5. Prescribed by or in consultation with a hematologist or an oncologist;
6. Request meets one of the following (a or b)*:
   a. Dose does not exceed 2.5 mg/kg of actual body weight intravenous every 3 weeks;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).
   *Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Multiple Myeloma (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or member has met initial approval criteria listed in this policy, or documentation supports that member is currently receiving Blenrep™ for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. Dose is ≥ 1.9 mg/kg every 3 weeks;
4. If the request is for dose increase, request meets one of the following (a or b)*:
   a. Dose does not exceed 2.5 mg/kg of actual body weight intravenous every 3 weeks;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).
   *Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval Duration
Commercial: 12 months

Medicaid: 12 months

References

1. National Comprehensive Cancer Network. Multiple Myeloma Version 5.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/myeloma_blocks.pdf. Accessed September 2, 2022.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	10/15/2020	12/07/2020
Policy was reviewed: 1) Initial Approval Criteria I.A.5.a and Continued Therapy Approval II.A.3.a were updated for better clarity from "2.5 mg/kg actual body weight" to "2.5 mg/kg (actual body weight) intravenous every 3 weeks". 2) Continued Therapy Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 3) References were reviewed and updated.	10/20/2021	12/07/2021
Policy was reviewed: 1. Initial Approval Criteria, I.A.3: Updated to include new prescribing criteria Prescribed as monotherapy. 2. Initial Approval Criteria, I.A.4: Updated trial and failure criteria from Member has received at least four prior chemotherapies, including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent to Member has received ≥ four (4) prior that include all of the following (a, b, or c); a. One anti-CD38 monoclonal antibody (e.g., Darzalex®/Darzalex Faspro™, Sarclisa®); b. One proteasome inhibitor	9/2/2022	10/19/2022

(e.g., bortezomib, Kyprolis®, Ninlaro®); c. One immunomodulatory agent (e.g., Revlimid®, pomalidomide, Thalomid®). 3. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 4. References were reviewed and updated.		
Policy was reviewed.	10/19/2023	10/19/2023